TO: Association Representatives FAX:

DATE: 10/9/96 SUBJECT: IVD Interim Policy

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Thank you.

This is to advise you of our interim policy regarding “Parents Access To Tests For Drugs of Abuse”.

Al Bracey, Associate Director for In-Vitro Diagnostics, Division of Small Manufacturers Assistance is the primary contact on this policy. He can be telephoned at 301-443-6597, 800-638-2041, extension #115, by fax at 301-443-8818 or Email at DSMO@FDADR.CDRH.FDA.GOV

PARENTS' ACCESS TO TESTS FOR DRUGS OF ABUSE

PURPOSE

This guidance describes how FDA will exercise its enforcement discretion for home test collection systems for drugs of abuse. It is intended to provide for the availability of home test collection systems sold directly to parents for use in the home setting, while FDA develops a final policy regarding the appropriate level of regulation of these products. FDA intends to exercise its enforcement discretion and not take any regulatory action against persons distributing such products during this interim period, so long as the criteria listed below are met. Once a final policy is in place, manufacturers and distributors will be expected to be in compliance, or come into compliance, with that final policy.

SCOPE

This guidance covers home test collection systems for drugs of abuse that are intended to be sold directly to parents for use in the home setting. The testing procedures for these products require that a specimen from the body (e.g., urine) be collected at home and mailed to a designated laboratory for testing. Test results are then communicated back to the parent.

CRITERIA

FDA intends to exercise its enforcement discretion during this interim period with respect to home test collection systems and their components that meet all of the following criteria:

1. The test(s) to be used by the laboratory have been cleared for marketing by FDA for identifying drugs of abuse in a laboratory setting;

2. The laboratory performing the test(s) has been certified by SAMHSA as having the necessary capability to reliably perform such test(s) or meets equivalent standards; and

3. The product ensures that samples are adequately identified to avoid mix-ups, and is accurately labeled so that parents can readily use it.

10/03/96